

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation, <i>et al.</i>)	
)	
Defendants.)	
)	

**DEFENDANTS' OPPOSITION TO DEPUY MITEK'S MOTION TO STRIKE
ARTHREX'S RELIANCE ON ITS OWN INTERROGATORY CONTENTIONS AND
DR. MUKHERJEE'S TIGERWIRE OPINIONS IN OPPOSITION TO DEPUY MITEK'S
MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT AND NO
INEQUITABLE CONDUCT**

Dated: October 4, 2006

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I. INTRODUCTION

Defendants Arthrex, Inc. (“Arthrex”) and Pearsalls, Ltd. (“Pearsalls”) (together, “defendants”) submit this Opposition to DePuy Mitek’s Motion to Strike Arthrex’s Reliance on its Own Interrogatory Contentions and Dr. Mukherjee’s TigerWire Opinions in Opposition to DePuy Mitek’s Motion for Summary Judgment of Infringement and No Inequitable Conduct (“Mitek Mot. to Str.”). For the reasons described hereinbelow, DePuy Mitek’s motion should be denied.

II. DEPUY MITEK FAILED TO COMPLY WITH LOCAL RULE 7.1(a)(2), AND THEREFORE, ITS MOTION SHOULD BE STRICKEN

Local Rule 7.1(a)(2) of the U.S. District Court for the District of Massachusetts requires that “[n]o motion shall be filed unless counsel certify that they have conferred and have attempted in good faith to resolve or narrow the issue.” In what has become a rather disturbing trend, for the second time in as many motion filings, DePuy Mitek made no attempt to comply with this local rule before filing its motion.

Just as was the case with the last motion filed by DePuy Mitek, prior to being served with the motion, defendants had no idea that DePuy Mitek objected to defendants’ citation of their interrogatory responses in their Opposition to DePuy Mitek’s Motion for Summary Judgment, or that DePuy Mitek objected to Dr. Mukherjee’s opinions related to TigerWire. Here again, had DePuy Mitek made *any* effort to comply with the local rules, defendants would have had the opportunity to explain why their interrogatory responses were used for non-hearsay purposes and why Dr. Mukerjee’s opinions on TigerWire are admissible. However, since DePuy Mitek did not contact defendants regarding its objections, this Court is once again forced to address the entirety of DePuy Mitek motion.

A. DePuy Mitek's Motion is Another Transparent Attempt to Circumvent The Page Limit Set Forth in Local Rule 7.1(b)(4)

Just as transparent as its last motion, this DePuy Mitek motion has all the trappings of an attempt to circumvent the Court's page limit. The issues raised by this motion could have, and should have, been raised in DePuy Mitek's Reply to its Summary Judgment Motion. The combined pages of this motion and the Reply was 26 pages, well in excess of the page limitation for motion papers. By filing a separate motion instead of including these arguments in its Reply, DePuy Mitek was able to extend the page limit of the Reply without seeking the defendants' consent or the permission of the Court. DePuy Mitek has now used this tactic twice and it should not be tolerated. On this basis alone, DePuy Mitek's motion should be denied without leave to refile.

III. SHOULD THE COURT CONSIDER DEPUY MITEK'S MOTION ON THE MERITS, THE MOTION SHOULD STILL BE DENIED

A. Defendants' Citation to Their Interrogatory Responses Was For Non-Hearsay Purposes

In an error that should prove to be fatal to its summary judgment motion for infringement, DePuy Mitek ignored two defenses raised by defendants in their interrogatory responses – *i.e.*, that the ends of FiberWire suture are tipped, thereby restricting the fiber mobility of the two dissimilar materials and the reverse doctrine of equivalents. As defendants explained in their summary judgment opposition, DePuy Mitek's omission of any arguments addressing these two defenses should be fatal to DePuy Mitek's summary judgment motion since it has effectively waived those arguments. Defendants' Opposition to DePuy Mitek's Motion for Summary Judgment of Infringement and No Inequitable Conduct ("Def's SJ Opp.") at 8-9. To find otherwise would be unfair to defendants since they do not have an opportunity to respond to DePuy Mitek's new arguments, raised for the first time in its reply. *See, e.g., Novosteel SA v. United States*, 284 F.3d 1261, 1273-74 (Fed. Cir. 2002) (holding "as a matter of litigation

fairness and procedure” arguments that did not appear in movant’s original summary judgment motion but did appear in movant’s reply brief were waived).

With regard to defendants’ identification of their two defenses, DePuy Mitek asserts that “Arthrex’s reliance on its contention interrogatory responses should be stricken,” since these responses are “not admissible by Arthrex because they are hearsay.” Mitek Mot. to Str. at 1. DePuy Mitek apparently misunderstands the reasons that defendants cited to the interrogatory answers. Defendants plainly did not offer their interrogatory responses for the truth of the matter asserted, but rather, the purpose was to alert the Court to the fact that there are two non-infringement defenses of which DePuy Mitek was aware (because they were raised in the interrogatory answers), but chose to ignore in its summary judgment motion. Such use is *not* hearsay because the interrogatory answers are not offered for the truth of the matter asserted. 2 MCCORMICK ON EVID. §§ 249, 295 (6th ed.).

1. Tipping materially affects FiberWire’s handleability

Apparently, DePuy Mitek is trying to create a world where it can neglect to raise appropriate issues in its motion, present evidence in a Reply only after its neglect is called to its attention, and then contend that defendants should not be permitted to file a substantive response. Even if the Court were to rule that DePuy Mitek’s failure to raise these issues in its original summary judgment motion was not a waiver, surely fairness demands that defendants be permitted to respond. *See, e.g., Cia. Petrolera Caribe, Inc. v. Arco Caribbean, Inc.*, 754 F.2d 404, 410 (1st Cir. 1985).

DePuy Mitek engages in such gamesmanship because it knows full-well that multiple witnesses in this case -- including witnesses for both Arthrex and DePuy Mitek -- have testified that the ends of suture are tipped in order to stiffen the ends so as to facilitate attachment to instruments, including needles, and/or to insert the suture through tissue -- all handleability

purposes. This was the testimony of Kevin Grieff, Shelby Cook, Ilya Koyfman and Gary McAlister. Ex. 1 at 53:23-54:2; Ex. 2 at 119:24-120:10; Ex. 3 at 106:5-10; Ex. 4 at 53:24-54:6. Thus, to the extent DePuy Mitek is not found to have waived its argument with regard to tipping -- as it rightfully should be -- the testimony of these several witnesses creates an issue of fact and DePuy Mitek's motion for summary judgment of infringement should be denied.¹

2. The Reverse Doctrine of Equivalents applies because FiberWire operates in a manner opposite to that of the '446 patent

As DePuy Mitek is also well aware, Dr. Mukherjee stated that the '446 patent specification describes that the first fiber-forming material is a lubricious material, and that the second fiber-forming material is added for strength. Ex. 5 at 7. Dr. Mukerjee also stated that the fact that the first fiber-forming materials are lubricious but too weak for most suture applications is further made clear by the specification which states that "a volume fraction [of lubricating yarns] above about 80% may adversely affect the overall strength of the braid." *Id.* He also noted that "there is a tradeoff between the properties of the two materials -- one being lubricious but weak, the other being added for strength," and that "the specification further recognizes that gains in handleability/pliability outweigh and loss of strength." *Id.* Likewise, Dr. Mukherjee stated that, in 1992, UHMWPE -- as used in FiberWire -- was a well-known, highly specialized fiber material with strength properties that are far superior to those of general purpose PE. Ex. 6

¹ DePuy Mitek also asserts that it is irrelevant whether FiberWire's ends infringe as long as the remainder of the suture infringes and cites two cases. Mitek's Reply in Support of its Motion for Summary Judgment of Infringement and No Inequitable Conduct ("Mitek's SJ Reply") at 4-5. Those cases, however, are inapposite since they address "comprising" claims and not "consisting essentially of" claims. It is well-known that one can not avoid infringement of a "comprising" claim simply by adding additional materials to the accused infringing product. The facts of this case are entirely different, however, since the transitional phrase is not "comprising," but "consisting essentially of." Thus, the question is not simply whether an unlisted ingredient has been added to an otherwise infringing product, but rather, whether the addition of that unlisted ingredient materially affects the handleability of the suture (*e.g.*, facilitating its insertion into needles, tissue, etc.). As demonstrated above, the adhesive does have such a material affect on the suture.

at 22. Further, as Dr. Brookstein acknowledged, UHMWPE is added to FiberWire for its strength, whereas PET is added for its flexibility. Ex. 7 at ¶ 56.

Having found this disclosure in the ‘446 patent, and with this explanation of the purposes of the materials used to make FiberWire, Dr. Mukherjee opined that “[t]he specification of the ‘446 patent describes that the first fiber-forming materials are added to improve suture handleability and that such materials are too weak for most suture applications. It is the second fiber-forming materials that are added for increased strength. The way in which the individual materials act in FiberWire is the opposite. UHMWPE that is added for strength and the PET is added to improve knot tying – a well-known handleability characteristic.” Ex. 5 at 18. This testimony establishes a defense under the reverse doctrine of equivalents. Thus, to the extent DePuy Mitek is not found to have waived its argument with regard to the reverse doctrine of equivalents -- as it rightfully should be -- Dr. Mukherjee’s statements create an issue of fact and DePuy Mitek’s motion for summary judgment of infringement should be denied.²

² DePuy Mitek stated that “it is not clear whether the reverse doctrine of equivalents is even a viable defense.” Mitek’s SJ Reply at 1. The Federal Circuit, however, has confirmed that it is a viable defense. For example, in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1351 (Fed. Cir. 2003), although the facts did not support a finding of reverse doctrine of equivalents, the Federal Circuit endorsed it as a viable defense and cited the Supreme Court in *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.* 339 U.S. 605, 608-09 (1950), cited Donald S. Chisum, 5A CHISUM ON PATENTS § 18.04 (1999), and also cited two other Federal Circuit opinions (*Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d. 1565, 1581 (Fed. Cir. 1991), and *Del Mar Avionics, Inc. v. Quinton Instr. Co.*, 836 F.2d. 1320, 1325 (Fed. Cir. 1987)).

Since *Amgen*, Judge Posner (N.D.Ill.) also recognized the doctrine of equivalents as a viable defense in *Smithkline Beecham Corp. v. Apotex Corp.*, 247 F.Supp.2d 1011, 1044-45 (N.D.Ill. March 3, 2003). He cited the Federal Circuit decision in *Amgen* and stated that the present case was a good case for the reverse doctrine of equivalents defense but since the defendant did not invoke it, he could not rely on it.

B. DePuy Mitek Cannot Strike the Additional Evidence That Shows That the Addition of Nylon to FiberWire Materially Affects the Basic and Novel Characteristics of the Claimed Invention

DePuy Mitek has apparently taken the position that since Dr. Mukherjee could not recall at his deposition every detail of every suture he evaluated in connection with this case, then that means Dr. Mukherjee did not review any sutures. Mitek Mot. to Str. at 4-5. That, of course, is not the law. A deposition is not a memory test, nor should it be treated as one. Dr. Mukherjee stated in his Responsive Expert Report that he “held a sample of both commercial FiberWire and TigerWire and the TigerWire felt stiffer and more coarse than the same sized FiberWire.” Ex. 5 at 30-31. Dr. Mukherjee also opined that “the coarse feel [of TigerWire] would suggest that the addition of the nylon would adversely affect knot tie-down.” Ex. 5 at 31. Dr. Mukherjee spent decades working in the suture industry and is highly qualified to opine on whether one suture feels stiffer and more coarse than another suture and what affect, if any, such coarseness would have on knot tie-down.

Unwilling to address this evidence head-on, DePuy Mitek’s tactic was to subject Dr. Mukherjee to a memory test at his deposition. The fact that Dr. Mukherjee did not recall every detail of every test he conducted while sitting for his deposition is unremarkable. What is notable, however, is the fact that DePuy Mitek intentionally did not ask Dr. Mukherjee about the specific statements he made in his expert report regarding his test of the stiffness and coarseness of TigerWire compared with FiberWire -- even after Dr. Mukherjee referred DePuy Mitek to his report where he says that nylon does affect pliability. Ex. 8 at 526:4-13. Rather, DePuy Mitek simply concludes, with a wave of the hand, that the tests were not conducted because Dr. Mukherjee did not remember every single test that he performed to support his opinions. Try as it may, DePuy Mitek can not sweep Dr. Mukherjee’s report under the rug in the hopes that it will disappear. Of course, Dr. Mukherjee conducted his test and his opinions were as stated in his

report. DePuy Mitek does not challenge Dr. Mukherjee's test as unscientific, nor does it challenge Dr. Mukherjee's qualifications to render any such opinion. The only attack on Dr. Mukherjee's test is a baseless conclusory statement that he did not conduct it. As explained above, that is simply not true.

DePuy Mitek spends four pages attacking Dr. Mukherjee's "drape" test as unscientific. Mitek Mot. to Str. at 5-8. But Dr. Mukherjee readily acknowledged that the drape test was not scientific and that his opinions in this case were not based solely on the drape test. Rather, the drape test was consistent with Dr. Mukherjee's other tests and merely served to confirm his opinions regarding TigerWire's pliability.

C. In Any Event, TigerWire Does Not Infringe for the Same Reasons That FiberWire Does Not Infringe

It is important to note that the addition of nylon to TigerWire simply provides defenses beyond those available for FiberWire. The infringement defenses applicable to FiberWire apply equally to TigerWire. Like FiberWire, TigerWire is also made of UHMWPE and PET (with nylon as a substitute for one of the PET filaments). Thus, TigerWire does not infringe because UHMWPE is not "PE" within the meaning of the '446 patent.

Similarly, TigerWire, just like FiberWire, is coated and the addition of the coating materially affects the basic and novel characteristics of the claimed invention. DePuy Mitek can not create a genuine issue of material fact on TigerWire by pointing to the testimony of Dr. Brookstein or Dr. Burks. Dr. Brookstein did no tests on TigerWire coating. Moreover, even if his 4.8% coating measurement³ on FiberWire applied to TigerWire, there is absolutely no

³ Defendants note that in their Reply Memorandum in Support of their Motion for Summary Judgment ("Def's Reply SJ Br."), they inadvertently misstated Dr. Brookstein's coating measurement. Instead of 3.4% coating by weight, Dr. Brookstein actually measured even more of a coating content on FiberWire -- 4.8% coating by weight.

support for Dr. Brookstein's opinion that 4.8% is a "very small amount of coating." In fact, all the evidence is to the contrary. *See* Def's Reply SJ Br. at 13-14.

Likewise, Dr. Burks' testimony can not create a genuine issue of fact. First, he did no tests on TigerWire. Second, his assertion (with respect to FiberWire) that differences were "subtle" has nothing to do with how FiberWire (or TigerWire) is used in a surgical environment. For his report, Dr. Burks tested FiberWire both "dry" and "wet." He explained that "wet" is how FiberWire is used in a surgical environment (Ex. 9 at ¶ 7) and that, with respect to all of his tests, "the difference between the two samples *was even more pronounced* when they were wet, which is how I am accustomed to using FiberWire." Ex. 9 at ¶¶ 11, 12. [Emphasis added.] Dr. Burks' comments about a subtle difference related *only* to "dry" FiberWire. Ex. 10 at 87:7-13.⁴ Notably, at his deposition, Dr. Burks was *not* asked a single question about his opinions on wet FiberWire, which is how it is used in the surgical environment. All of DePuy Mitek's questions were directed to his opinions on "dry" FiberWire. Thus, Dr. Burks' opinion that the differences were "more pronounced" when wet, as the product is actually used, remains unrebutted. As defendants previously stated, if the affect of the unlisted material is of importance or of consequence to those of ordinary skill in the art -- here Dr. Burks believes there is a "pronounced" difference -- it is a "material" affect. *PPG Indus. v. Guardian Indus. Corp.* 156 F.3d 1351, 1354 (Fed. Cir. 1998).

IV. CONCLUSION

For all the foregoing reasons, DePuy Mitek's motion should be denied.

⁴ At his deposition, Dr. Burks was only asked to perform tests on "dry" FiberWire, where the differences are less pronounced. Even here, he got the answer correct each time.

Dated: October 4, 2006

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing DEFENDANTS' OPPOSITION TO DEPUY MITEK'S MOTION TO STRIKE ARTHREX'S RELIANCE ON ITS OWN INTERROGATORY CONTENTIONS AND DR. MUKHERJEE'S TIGERWIRE OPINIONS IN OPPOSITION TO DEPUY MITEK'S MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT AND NO INEQUITABLE CONDUCT was served, via the Court's email notification system on the following counsel for Plaintiff on the 4th day of October 2006:

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EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a
Massachusetts Corporation,

Plaintiff,

vs.

Arthrex, Inc., a Delaware
Corporation,

Defendant.

COPY

CIVIL ACTION
NO. 04-12457 PBS

DEPOSITION OF:

KEVIN GRIEFF

DATE:

September 15, 2005

TIME:

9:15 a.m. to 11:23 a.m.

LOCATION:

The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY:

Plaintiff

REPORTER:

Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER:

Les Smoak, CLVS

1 A. I don't know how it would be different at
2 Pearsalls, but, obviously, there would be a difference
3 because it's a loop. I have no knowledge of how that's
4 done.

5 Q. So is it your understanding that Pearsalls loops
6 the FiberWire used to make the Arthrex FiberLoop product?

7 A. Pearsalls is the manufacturer of that. How they
8 do it, I don't know.

9 Q. Now how does the manufacturing of Arthrex's
10 FiberStick differ than -- strike that.

11 How does the manufacturing of Arthrex's
12 FiberStick product differ than the manufacturing of
13 Arthrex's FiberWire product?

14 A. It does not. It goes through the same processes
15 with the same entities.

16 Q. Okay. Then how -- how is the FiberStick product
17 different than the FiberWire product?

18 A. It has a longer tipping.

19 Q. And who does the tipping?

20 A. R.K. Manufacturing.

21 Q. And is the tipping just a longer portion of --
22 well, strike that.

23 What is the tipping process used for
24 manufacturing Arthrex's FiberStick?

25 A. I'm not sure of the exact process, but tipping is

1 to make the suture rigid so you can pass it through
2 instruments.

3 Q. Mmm-hmm.

4 A. The FiberStick just may have I believe 8 or
5 9 inches of tipping versus 1 inch of tipping.

6 Q. So other than the tipping for FiberStick, there's
7 no other difference in the manufacturing process between
8 FiberStick and FiberWire?

9 A. No, sir.

10 Q. How does the manufacturing of Arthrex's
11 FiberSnare product differ than Arthrex's manufacturing of
12 the FiberWire product?

13 MR. TAMBURO: Objection to form.

14 A. I'm not that familiar with the FiberSnare
15 product, but I do not believe it's any different. It goes
16 through -- it definitely goes through Pearsalls and R.K.

17 Q. Do you know what product number the FiberSnare is
18 or what part number the FiberSnare?

19 A. 7209. AR-7209.

20 That's incorrect. That was the FiberStick. The
21 FiberSnare, 7209SN.

22 Q. So AR-7209 SN is the FiberSnare product?

23 A. Correct.

24 Q. And that product, FiberSnare, is listed on Page
25 ARM 18537 of Exhibit 101. And I believe that's Page 12-5

EXHIBIT 2

Confidential Deposition of:
Shelby Cook Kornbluth

November 15, 2005

Page 1

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF MASSACHUSETTS

3 C.A. No. 04-12457 PBS

4 * * * * *

COPY

5 DePUY MITEK, INC.,

6 Plaintiff

7 v.

8 ARTHREX, INC., a Delaware

9 corporation,

10 Defendant

11 * * * * *

12 VOLUME I

13 PAGES 1-245

14

15 DEPOSITION OF DePUY MITEK, INC. by

16 SHELBY COOK KORNBLUTH, a witness called on

17 behalf of the Defendant, pursuant to the

18 Federal Rules of Civil Procedure, before

19 Jessica L. Williamson, Registered Merit

20 Reporter, Certified Realtime Reporter and

21 Notary Public in and for the Commonwealth of

22 Massachusetts, at the Hilton Hotel, 25

23 Allied Drive, Dedham, Massachusetts, on

24 Tuesday, November 15, 2005, commencing at

25 9:01 a.m.

Confidential Deposition of:
Shelby Cook Kornbluth

November 15, 2005

Page 119

1 A. Correct.

2 Q. -- of the whole concentrate?

3 A. Correct.

4 Q. Okay. And then what actually sticks is the
5 .07 to the .15 percent, and that's the
6 vol -- that's measured as a percentage of
7 the volume of the suture?

8 A. Yes.

9 Q. And is that range, the .07 to .15, the same
10 for the violet and blue?

11 A. Yes.

12 Q. Are there any other components of the
13 Orthocord -- we've mentioned the ultra high
14 molecular weight PE, the PDS, the two
15 fibers, the coating. I think you mentioned
16 the dye earlier --

17 A. Uh-huh.

18 Q. -- right? One's a blue dye, one's a violet
19 dye. Anything else?

20 A. The suture is -- has a tip at each end.

21 Q. And what is the tip made of?

22 A. God, it's a combination of four different
23 materials. They escape me right now.

24 Q. Okay. What is the purpose of tipping the
25 suture?

Confidential Deposition of:
Shelby Cook Kornbluth

November 15, 2005

Page 120

1 A. The original intent of tipping the suture is
2 so that you can -- that the end of the
3 suture is stiff enough to insert into a
4 needle to attach or for a surgeon to put
5 through a free needle so that they can use a
6 suture without a needle on it.

7 Q. So it's stiff enough to put it on the
8 needle? Is that part of the manufacturing
9 process, the first thing you described --

10 A. Yeah.

11 Q. -- what Ethicon or one of these other
12 companies does?

13 A. When they attached the suture to the
14 needle --

15 Q. Yes.

16 A. -- if you don't have a tip on there, you
17 can't get it into the needle hole.

18 Q. Right. So that's part of the manufacturing
19 process? That's the first purpose --

20 A. Yes.

21 Q. -- of tipping?

22 And the second purpose has to do with
23 the surgeon?

24 A. Yeah, over -- I mean, over the years suture
25 companies have added a tip to the tips of

EXHIBIT 3

Confidential Deposition of:
Ilya Koyfman

February 22, 2006

Page 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
C.A. No. 04-12457 PBS

-----X
DePUY MITEK, INC.,

A Massachusetts Corporation,

Plaintiff,

v.

ARTHREX INC.,

A Delaware Corporation,

Defendants.
-----X

* * *CONFIDENTIAL* * *

DEPOSITION OF ILYA KOYFMAN

Somerset, New Jersey

February 22, 2006

Reported by:

MARY F. BOWMAN, RPR, CRR

JOB NO.: SE232

Confidential Deposition of:
Ilya Koyfman

February 22, 2006

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1 KOYFMAN - Confidential
2 core. You have an internal core and then you have
3 a sheath which is braided sheath, right? So if
4 you have a suture which -- you cut the suture
5 length and you tip it, the tipping is a relatively
6 rigid polymeric substance which allows for
7 insertion of a suture into the needle. So you
8 need this tip. So if you have a tip on both ends
9 like in the case with Orthocord, you basically
10 anchor two ends.

11 So if you have sheath too mobile, you
12 know, you can displace some of that amount of
13 sheath over the core and you can -- and you can
14 accumulate it in one part. That's -- that has
15 to be -- the amount of how much you can
16 accumulate or the relationship to the initial
17 diameter has to be specified.

18 This phenomena is called bunching, so
19 basically you bunch up, bunch it.

20 Q. A part of the suture at one end?

21 A. Yes.

22 Q. That is a characteristic you are
23 trying to avoid, bunching?

24 A. You try to minimize it.

25 Q. Why do you try to minimize bunching?

EXHIBIT 4

Confidential Deposition of:
Gary B. McAlister

December 22, 2005

Page 1

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF MASSACHUSETTS

3 C.A. No. 04-12457 PBS

4 * * * * *

COPY

5 DePUY MITEK, INC.,

6 Plaintiff

7 v.

8 ARTHREX, INC., a Delaware

9 corporation,

10 Defendant

11 * * * * *

12 VOLUME 1

13 PAGES 1-197

14
15 DEPOSITION OF GARY B. McALISTER, a
16 witness called on behalf of the Defendant,
17 pursuant to the Federal Rules of Civil
18 Procedure, before Jessica L. Williamson,
19 Registered Merit Reporter, Certified
20 Realtime Reporter and Notary Public in and
21 for the Commonwealth of Massachusetts, at
22 the Four Points Sheraton, 1125 Boston
23 Providence Turnpike, Norwood, Massachusetts,
24 on Thursday, December 22, 2005, commencing
25 at 8:59 a.m.

Confidential Deposition of:
Gary B. McAlister

December 22, 2005

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1 me about learning from the Orthocord team?

2 A. No, not -- what I also -- already said was
3 about making it a carrier for other kinds of
4 antimicrobials or other kinds of drugs.

5 Q. Is that something that you learned from the
6 Orthocord team, or is that --

7 A. I learned that at Mitek.

8 Q. But was that from something other than the
9 Orthocord team?

10 A. It was related as we talked about new suture
11 products going on and other things that
12 might be of interest in the suture line to
13 Mitek. We were informed of that project and
14 that product that was released through
15 Ethicon.

16 Q. With respect to the Orthocord product, do
17 you have any knowledge with respect to the
18 tipping of the Orthocord product, the
19 materials used for tipping?

20 A. No.

21 Q. Do you have any knowledge as to why the --
22 is the product tipped?

23 A. Yes.

24 Q. Okay. Do you have any knowledge as to why
25 the product's tipped?

Confidential Deposition of:
Gary B. McAlister

December 22, 2005

Page 54

1 A. Yes.

2 Q. Okay. And what is that?

3 A. It makes it easier to thread through --
4 either through an anchor or through tissue.

5 Q. Through a needle as well?

6 A. Yes. Through anything, yeah.

7 Q. Anything else about why the products are
8 tipped?

9 A. No.

10 Q. And what is the basis of your knowledge of
11 the -- why the Orthocord suture is tipped?

12 A. It came from the Orthocord team.

13 Q. Same people we talked about or any others?

14 A. Same people.

15 Q. Do you have any direct experience with
16 tipping of suture?

17 A. No.

18 Q. Do you have any other source of knowledge as
19 to why suture is tipped other than through
20 the Orthocord team?

21 A. The only other member from the Orthocord
22 team might be one of the marketing people
23 who has direct contact with the customer.

24 Q. Okay. And who would that be?

25 A. Jon Grange most likely.

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

RESPONSIVE EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE
CONCERNING NON-INFRINGEMENT OF U.S. PATENT NO. 5,314,446
AND OTHER MATTERS

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his responsive expert report concerning non-infringement and other matters as follows.

that while such braids will be highly pliable, they will also be relatively weak and unusable for most suture applications. Ex. 3 at col. 2, ll. 22-25.

The proposed solution described in the '446 patent is a heterogeneous braid made up of two dissimilar materials. According to the specification, the braid is made up of a first fiber-forming material mechanically interlocked or weaved with a second fiber-forming material. The specification also states that the first fiber-forming material is a lubricious material, and that the second fiber-forming material is added for strength. The fact that the first fiber-forming materials are lubricious but too weak for most suture applications is further made clear by the specification which states that "a volume fraction [of lubricating yarns] above about 80% may adversely affect the overall strength of the braid." As described throughout the specification, there is a tradeoff between the properties of the two materials – one being lubricious but weak, the other being added for strength. The specification further recognizes that gains in handleability/pliability outweigh any loss of strength.

The specification also repeatedly states that the advantage of the above-described braid construction is that the braid exhibits improved handleability and pliability without appreciably sacrificing its physical properties. Ex. 3 at col. 2, ll. 32 – 37; ll. 62 – 66; col. 6, ll. 7 – 8.

Claim 1 of the '446 patent is to a surgical suture, the surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous

- C. UHMWPE is used in FiberWire to impart strength and PET is used in FiberWire to improve handleability

As I previously mentioned, the specification of the '446 patent describes that the first fiber-forming materials are added to improve suture handleability and that such materials are too weak for most suture applications. It is the second fiber-forming materials that are added for increased strength. The way in which the individual materials act in FiberWire is the opposite. UHMWPE that is added for strength and the PET is added to improve knot tying – a well-known handleability characteristic.

- D. The basic and novel characteristics described in the '446 patent are a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties

I have been asked to provide my opinion regarding what a person of ordinary skill in the art in February 1992 would understand to be the basic and novel characteristics described in the '446 patent. It is my opinion that a person of ordinary skill in the art, in February 1992, reading the specification of the '446 patent would understand the basic and novel characteristics to be a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification. Ex. 3 at col. 2, ll. 32 – 37; ll. 62 – 66; col. 6, ll. 7 – 8.

The specification also describes that there is a tradeoff between the two fiber-forming materials that make up the two dissimilar yarns – one being lubricious, but

Based on my review of the three micrographs, it appears that they are very different and that they are too unclear to draw any conclusions from them. Despite the lack of clarity, however, it appears that the individual braid filaments are grouped together to a much greater degree in the Tab G micrograph than they are in the Tab E micrograph. This is an indication that coating has permeated into the braid.

In any event, Dr. Brookstein's conclusions are inconsistent with the findings discussed below. In addition to the tests described above, CETR also conducted a scanning electron microscopy (SEM) examination of coated and uncoated FiberWire suture. My review of the scans performed to date appears to indicate that the coating does extend into the braid. Ex. 20 at Fig. 14. This is consistent with the effect coating has on FiberWire's pliability, as described above.

F. The nylon added to TigerWire suture materially affects its pliability

I understand that Arthrex's TigerWire suture has the same construction as FiberWire suture except that one of the PET carriers is replaced with nylon 6,6. All the reasons discussed in connection with FiberWire also apply to TigerWire. Further, it is well known in the art of manufacturing and/or processing of fibers that nylon 6,6 fibers of the type used in TigerWire are generally more stiff (i.e., less pliable) than fibers made of PET, as used in FiberWire and TigerWire. Ex. 26. Therefore, the act of removing one PET carrier and replacing it with a nylon 6,6 carrier during the braiding process, as is done with TigerWire, introduces a less pliable material into the composite braid.

It is also my understanding from discussions with Bill Benavitz of Arthrex that the diameter of the nylon 6,6 fibers used in TigerWire is greater than that of the PET which it replaces. Therefore, the nylon 6,6 fiber makes up a greater percentage of the braid cross-section area than does the PET fiber it replaces. Mr. Benavitz also informed me that Arthrex has received customer feedback that TigerWire is more stiff than FiberWire. In addition, I held a sample of both commercial FiberWire and TigerWire and the TigerWire felt stiffer and more course than the same sized FiberWire. I also conducted the drape test on the two samples and found that the FiberWire conformed to the shape of my finger to a much greater degree than the TigerWire, indicating that the addition of the nylon appears to make TigerWire stiffer and less pliable. For these reasons, it is my opinion that the addition of nylon 6,6 in TigerWire materially affects its pliability. Moreover, the course feel would suggest that the addition of the nylon would adversely affect knot tie-down.

Dr. Brookstein stated that the purpose of the nylon included in TigerWire is for visual identification, and refers to Peter Dreyfuss's testimony to support his opinion. Brookstein Report at ¶ 46. Whether or not Dr. Brookstein's report is accurate, it does not change the fact that, as explained above, the addition of nylon materially affects TigerWire's pliability.

- G. Adding an adhesive to FiberStick suture materially affects its handleability

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE
CONCERNING INVALIDITY OF U.S. PATENT NO. 5,314,446

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his expert report as follows.

I have been informed by Mr. Witherspoon that in order for a patent to be valid, the specification must meet the "written description" requirement of 35 U.S.C. § 112, which means that it must reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed. I further have been informed that in order for a patent to be valid, it must also satisfy the "enablement" requirement of section 112. That is, I have been informed that one must determine whether the specification, viewed from the perspective of a person skilled in the art, teaches such a person how to make and use the claimed invention without having to resort to undue experimentation.

It is my opinion that the '446 patent specification as filed in 1992 does not reasonably convey to one of ordinary skill in the art that the inventors had possession of UHMWPE. There is no disclosure at all within the '446 patent of using UHMWPE as a suture material. In February 1992, UHMWPE was a well-known, highly specialized fiber material with strength properties that are far superior to those of general purpose PE. Consequently, the two materials are generally used for very different applications and one is not a substitute for the other. It has been my experience that, generally, when UHMWPE is intended to be included for a specified application, there is a special effort to make that fact known. For example, the '575 patent, the Burgess application, the Cohan article, Arthrex's U.S. Patent No. 6,716,234, covering its FiberWire suture, Plaintiff's patent application no. 2005/0149118, covering its Orthocord suture and

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Expert Report of Dr. David Brookstein

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and

56. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHMWPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

57. In my opinion, the "way" of the first fiber-forming material is the same as the "way" of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	"Way" of Limitation Under the Doctrine of Equivalents	Way UHMWPE performs its Function in FiberWire™ and TigerWire™
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The "way" is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set.	At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Dreyfuss 9/16/05 Dep. at p. 99-107).

58. My opinion regarding the "way" of the "first fiber-forming" element is supported by the '446 Patent. The '446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact. For example, the '446 Patent states in the "Summary of the Invention" section that the "the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction" and that the at least one yarn from the first set is in "direct

EXHIBIT 8

417

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF MASSACHUSETTS

3 Civil Action No. 04-12457 PBS

COPY

4 -----
5 DEPUY MITEK, INC., a Massachusetts)

6 Corporation,)

7 Plaintiff,)

8 v.)

9 ARTHREX, INC., a Delaware Corporation)

10 Defendant.)

11 -----)

12
13
14 Videotaped Deposition of DEBI PRASAD MUKHERJEE

15 - VOLUME TWO -

16 Washington, DC

17 Wednesday, June 14, 2006

18
19 The videotaped deposition of DEBI PRASAD MUKHERJEE,

20 Volume Two, was held on Wednesday, June 14, 2006,

21 commencing at 9:12 a.m., at the offices of Dickstein

22 Shapiro Morin & Oshinsky LLP, 2101 L Street,

23 Northwest, Washington, DC, before Mary Ann Payonk,

24 RDR, Certified Realtime Reporter, Registered Diplomat

25 Reporter and Notary Public.

526

1 A Because that's not my decision to do what
2 test -- what samples to be tested so I didn't go to
3 TigerWire.

4 Q Do you have an opinion about how -- do you
5 know that TigerWire has one nylon --

6 A Yes.

7 Q -- strand in it?

8 And do you have an opinion about how that
9 nylon strand affects TigerWire's pliability?

10 A It's in my report. The nylon will
11 affect --

12 Q Okay.

13 A -- the pliability.

14 Q Did you do any -- why didn't Dr. Gitis do
15 some TigerWire pliability tests to determine the
16 effect of nylon?

17 A I cannot answer. I do not know.

18 Q Is it required to -- for -- to have a
19 pliability test that Dr. Gitis did in order to
20 determine the effect of nylons on the pliability of
21 FiberWire?

22 MR. TAMBURO: Objection, vague.

23 A Probably.

24 BY MR. BONELLA:

25 Q Okay. Where were you given the -- the

EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

EXPERT REPORT OF ROBERT T. BURKS, M.D.

1. I am an orthopaedic surgeon with the University of Utah Orthopaedic Center. My office is at 590 Wakara Way, Salt Lake City, Utah 84108. I have been practicing for more than 23 years.
2. I received my M.D. from St. Louis University in 1974. I completed a residency in Orthopaedics at the University of California at San Diego in 1983. I completed a knee and sports medicine fellowship at Kaiser Permanente Hospital in San Diego in 1983, and sabbatical at Steadman Hawkins in Vail, Colorado in 1995
3. I am a Professor and Mary Scowcroft Peery Presidential Endowed Chair at the University of Utah Health Sciences Center. I am also the Director of Sports Medicine and Head Physician at the University of Utah. My curriculum vitae are attached as Exhibit 1.

4. My specialties include arthroscopy of the shoulder, knee and ankle, and ligament reconstruction. My research interests include patella stability, cartilage defects, tendon healing to bone.

5. I have reviewed Dr. Fenton's report and I understand he may provide testimony on certain subjects including human anatomy, surgical techniques and surgical devices. I may also provide testimony on these same subjects.

6. I may describe the characteristics of a surgical suture that are generally important to an orthopaedic surgeon. I may also describe the specific features of FiberWire that I find beneficial in my practice.

7. I have been using FiberWire suture in my surgical procedures since 2001. Most of my subjective use of FiberWire occurs during surgery and in the surgical environment, FiberWire is generally wet.

8. Sometime in February 2006, I was contacted by attorneys for Arthrex, Inc. and asked to conduct a tactile feel analysis as well as a knot tie-down analysis of coated and uncoated FiberWire suture. I agreed to conduct the analysis.

9. In March 2006, I received two samples of suture labeled "suture A" and "suture B." Each sample was on a spool and was approximately 3 meters in length. I was told by Arthrex's attorneys that one sample was coated US No. 2 FiberWire and that the other sample was uncoated US No. 2 FiberWire, however, I was not told which sample was coated and which was uncoated.

10. I took the sutures and cut them into some lengths that are appropriate for intraoperative tying and for intraoperative knot tying done arthroscopically. This allowed 5 strands from each spool.

11. I conducted a tactile feel analysis of both suture samples ("suture A" and "suture B"). During the analysis, I noticed that the sample labeled "suture A" generally felt smoother than "suture B." The difference between the two samples was even more pronounced when they were wet, which is how I am most accustomed to using FiberWire.

12. I also conducted a knot tie-down analysis on the two suture samples. I tied several surgeons knots and found that the knots slid easier on the sample labeled "suture A" as compared with the sample labeled "suture B." I felt less friction when sliding the knot on the sample labeled "suture A" as compared with the sample labeled "suture B." Here again, the difference between the two samples was most noticeable when they were wet, as I am accustomed to using FiberWire.

13. After conducting my analysis, I was informed that "suture A" was the coated FiberWire and "suture B" was the uncoated FiberWire.

14. If asked to testify at trial, I may use physical exhibits, as well as other demonstrative exhibits, which have not yet been developed.

EXHIBIT 10

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

-0-

COPY

DEPUY MITEK, INC., a
Massachusetts Corporation,

Plaintiff,

-vs-

ARTHREX, INC., a Delaware
Corporation, and PEARSALLS
LTD., a Private Limited
Company of the United
Kingdom,

Defendants.

:
Civil Action No.
: 04-12457 PBS

:

:

: EXPERT DEPOSITION OF:
: ROBERT T. BURKS, M.D.

:

-0-

Location: Marriott University Hotel
Salt Lake City, Utah

Date: June 7, 2006
3:00 p.m.

Reporter: Denise Kirk, CSR/RPR

-0-

1 I described them.

2 Q. Okay, so why did you use the particular
3 knots, then, that you used in the knot tie-down
4 analysis?

46:51 5 A. I just tried to reproduce what I do in the
6 operating room.

7 Q. In paragraph 11 in Exhibit 232 you state
8 that suture A generally felt smoother than suture B.
9 What do you mean by "generally"?

47:08 10 A. The differences between the sutures were
11 subtle. I mean, they were not sharp, distinct. So I'm
12 meaning that in comparing them, my take was that it
13 was generally smoother.

47:45 14 Q. Were there any of the sutures in the
15 tactile feel analysis where you couldn't tell the
16 difference between suture A and suture B?

17 A. It was not my intent at the time in
18 looking at the sutures to compare each strand side to
19 side. My intent was to look at sort of spool A and
48:13 20 spool B. So it was to get a feel of, in general, how
21 do they feel between the two.

22 So I didn't take a strand and say is this
23 one different? And is this one different? And go
24 down through that five times, because I felt it was
4 '8 25 all the same suture.